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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

August 6, 1998

WARNING LETTER
CHI-35-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John C. Mills
Chairman of the Board & CEO
Dentsply International, Inc.
P.O. Box 872
570 W. College Ave
York, PA 17405-0872

Dear Mr. Mills:

During an inspection of the Franklin Park, Illinois facility of MPL Technologies (a division of Dentsply, Inc.), from June 1 to 16, 1998, Investigator James Finn determined that MPL Technologies is a manufacturer of medical and dental needles. Medical and dental needles are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to ensure that the process used to manufacture medical and dental needles will consistently produce non-pyrogenic needles. The validation of the dry heat sterilization process for depyrogenation efficiency was performed in July 1993. The validation did not include a challenge of the worst case parameters. Further significant changes to the process have been made since the validation was completed. Also, the water used to rinse the cannulas (at several steps in the process) is not tested for endotoxin and there is no routine cleaning and maintenance program currently in effect for the water system.

2. Failure to verify or validate changes to the manufacturing process to ensure that product will meet specifications. For example, new injection molding machines were put into service, changes were made to the dry heat sterilization cycle and mold tooling changes were made. These changes were not evaluated to determine their effect on the integrity of the sterile packaging.

This letter is not intended as an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter, and in the Form FDA 483 (enclosed) issued to Mr. Gustav A. Scheuble at the closeout of the inspection, may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge receipt of Mr. Gustav A. Scheuble's response to our Form FDA 483, dated June 23, 1998. We find the response adequately addresses our concerns. However, we require verification of correction either by FDA inspection or by a third party auditor's written verification.

Until FDA has documentation to establish that such corrections have been made, Federal agencies will be advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

You should take prompt action to prevent a repeat of these deviations. Failure to prevent these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing whether you will contract a third party audit or whether you would prefer FDA to perform a reinspection.

Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Enclosure

cc: Mr. Gustav A. Scheuble
Vice President & General Manager
MPL Technologies, Division of Dentsply, Inc.
9400 King St.
Franklin Park, IL 60131